

REMARKS

Claims 2-10 and claims 58-61 are pending in the present application. Claim 2 was amended as requested by the Examiner. Claim 4 has been canceled without prejudice and without acquiescence. Applicants retain the right to file a continuation and/or a divisional application to any canceled claims. No new matter has been added.

The issues outstanding in this application are as follows:

- Claim 2 was objected because of informalities.
- Claims 2-4 and 58-61 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of co-pending application No. 10/475,502.
- Claims 2-10 and 58-61 were rejected under 35 U.S.C. § 101 as allegedly lacking an specific or well-established utility.
- Claims 2-10 and 58-61 were rejected under 35 U.S.C. § 112, first paragraph.
- Claims 2-10 and 58-61 were rejected under 35 U.S.C. § 112, second paragraph.

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Claim Objection

Claim 2 is objected as containing informalities. In order to advance prosecution, Applicants amended the claim as suggested by the Examiner.

II. Provisional Double Patenting Rejection

Claims 2-4 and 58-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of co-pending application No. 10/475,502. Applicants traverse.

Applicants request that this rejection be held in abeyance until the conflicting claims are in fact patented.

III. Rejection under 35 U.S.C. § 101

Claims 2-10 are rejected under 35 U.S.C. § 101 as lacking a specific or well established utility. Applicants respectfully traverse.

The present rejection as a whole is improper as the PTO has not met its burden to establish a *prima facie* case of lack of utility. For example, the Office states that all the asserted utilities that it lists by page and line number are general utilities and are not considered specific or substantial because there is no disclosed signaling pathway associated with SEQ.ID.NO. 1 or that there is not a specific disease or cell-proliferative disorder associated with SEQ.ID.NO. 1. Applicants respectfully traverse.

Applicants assert that it is irrelevant to the utility of the application if the entire mechanism or signaling pathway by which SEQ ID NO. 1 modulates fertility is known or understood; the asserted utility that SEQ ID NO. 1 modulates fertility is clearly established and meets the requirements of a practical or “real world” utility. *See Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

In fact, Applicants are confused as to why the Examiner needs the entire mechanism or signaling pathway in order to establish utility. Applicants note that whether a mechanism by which a chemical or biological process is accomplished is unknown and whether that process works are two different questions. The fact that the exact mechanism by which the

proteins effect fertility is unknown is irrelevant to the patentability of the claims presented herein, and certainly irrelevant to the established utility.

The Examiner and Applicants have each listed specifically by page and line number the various suggested functions or activities concerning the claimed polynucleotides. In the response filed by the Applicants on July 14, 2004, the Applicants provided further evidence which confirmed some of the asserted utilities, more particularly the relationship between the polynucleotide and fertility (See 1.132 declaration filed July 14, 2004 by Martin M. Matzuk and the publication Wu et al., *Nature Genetics* 33:187-191, 2003). Although the Wu et al publication may indicate testes expression as stated by the examiner, the publication clearly confirms that SEQ ID NO. 1 effects fertility (e.g., ovarian development, oogenesis, and embryonic development).

As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. Applicants assert that they have provided documentary evidence, which the Examiner appears to have overlooked. For example, in the Wu et al. publication it clearly establishes that Zar1 homozygous knockout mice ($Zar1^{-/-}$) are infertile, and Zar 1 and SEQ ID NO. 1 are similar polynucleotides, thus the present invention has utility, in that it has a “real world” use or application in the world of fertility.

In view of the above statements, Applicants assert that the specification does disclose how to use the polynucleotide and thus, sets forth a specific and substantial utility and/or a well-established utility. If, however, the Examiner continues to maintain a *prima facie* case of non-utility, then the Applicants respectfully request that the criteria be indicted in the next Action, more specifically support for factual findings relied upon in reaching this conclusion; and an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. Applicants remind the Examiner that if the Office cannot develop a proper *prima facie* case and provide evidentiary support for a rejection under 35 U.S.C. 101, then a

rejection on this ground should not be imposed. See, for example, *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

IV. Rejection under 35 U.S.C. § 112

A. 35 U.S.C. § 112, first paragraph

Claims 2-10 and claims 58-61 are rejected under 35 U.S.C. § 112, first paragraph since the claimed invention lacks a specific or well established utility. Applicants respectfully traverse.

Applicants assert that the claimed invention has an asserted utility as discussed above under the utility rejection. Thus, in view of the above comments, Applicants request that the rejection be withdrawn in conjunction with the utility rejection.

B. 35 U.S.C. § 112, second paragraph

Claims 2-10 and claims 58-61 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully traverse.

In order to advance prosecution of the application, Applicants have canceled claim 4 without prejudice and without acquiescence.

With regards to claims 58 and 60, Applicants asserts that the term “specifically hybridizes” is not relative and does not render the claim indefinite. As noted in the application, stringent hybridization conditions are used to avoid non-specific binding (See page 11, lines 22-25), thus one of skill in the art understands that conditions are used such that there is specific hybridization. In view of this argument, Applicants request that the rejection be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. 10411469 from which the undersigned is authorized to draw.

Dated: December 20, 2004

Respectfully submitted,

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